Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Evaluation of the effect of ginger as an adjunct therapy along with SSRIs to reduce anxiety inpatients with Generalized Anxiety Disorder (GAD)

Protocol summary

Study aim

Determining the adjuvant effects of ginger capsules on the reduction of generalized anxiety disorder in concomitant use of SSRIs compared with placebo, which means in comparison with the reduction of generalized anxiety disorder in patients taking SSRIs and starch capsules

Design

This study is a phase 2 3 clinical trial with eighty participants. Forty patients in intervention group: SSRI drug with specific dose + two capsules of 500 mg of ginger per day Forty patients in control group: SSRI drug with specific dose + two starch capsules per day For randomization, we will use the method of foursome Block Randomization. (Two intervention sheets and two control sheets and random selection between these four sheets for each patient until the completion of four sheets then repeating this procedure)

Settings and conduct

This study is a randomized clinical trial which will be performed on patients with generalized anxiety disorder referred to the psychiatric clinic of Sina Hospital or a psychiatrist's private office within 12 weeks (while taking given SSRI drug with ginger or starch). The patients will be blinded whether they are taking ginger or placebo beside the SSRI drug

Participants/Inclusion and exclusion criteria

Diagnosis of generalized anxiety disorder by the physician and the patient's informed consent to participate in the study, the participants being in the age group of 18 to 65 years old and not having an accompanying disease, and also the participants should not be pregnant or breastfeeding

Intervention groups

Eighty patients with generalized anxiety disorder with study criteria are randomly divided into two intervention or control groups, the first group is given SSRI drug and ginger rhizome powder capsules and the group Second, we give SSRIs and placebo capsules

Main outcome variables

The severity and extent of recovery from anxiety according to Hamilton Anxiety Rating Scale

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201108049306N1**
Registration date: **2021-01-29, 1399/11/10**
Registration timing: **prospective**

Last update: **2021-01-29, 1399/11/10**
Update count: **0**

Registration date

2021-01-29, 1399/11/10

Registrant information

Name

Sina Anaraki

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3775 0343

Email address

sinaanaraky@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-03-05, 1399/12/15

Expected recruitment end date

2021-09-06, 1400/06/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of ginger as an adjunct therapy along with SSRIs to reduce anxiety inpatients with Generalized Anxiety Disorder (GAD)

Public title

Evaluation of ginger as an adjunct therapy in Generalized Anxiety Disorder

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Diagnosis of Generalized Anxiety Disorder by a physician based on the Hamilton Anxiety Rating Scale The patient has filled in the consent form and consciously enters the study and cooperates Age group 18 to 65 years old

Exclusion criteria:

The patient is pregnant or breastfeeding The patient has a major co-morbid psychological disorder (including depressive disorder, bipolar disorder, psychosis, and drug use) The patient has taken any antioxidant medication or supplement in the past month Taking medicine that has interaction with ginger The patient has co-morbid disease (other than neurological diseases)

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

The method of block randomization with individual units by preparing four sheets of paper. On the two sheets we write the letter "I" meaning "Intervention" and on the other two sheets we write the letter "P" meaning "Placebo". Mix the sheets together and place them in the desk drawer. With the referral of each eligible patient, one of the sheets is randomly pulled out and based on this sheet whether it is "I" or "P", they will be assigned to one of the two intervention or control groups.

Blinding (investigator's opinion)

Double blinded

Blinding description

Patients are blinded that they are taking ginger or starch capsules and all of them are told they are taking ginger capsules along with the prescribed SSRI. The researcher is also blind to whether patients are receiving ginger or not (Only the doctor or clinical caregiver is not blinded). The method of blinding is that the doctor who has four sheets in his desk drawer (two "i" sheets that means "Intervention" and two "p" sheets that means "Placebo") by referring to each of the eligible patients, one of the sheets Randomly taken out and based on this sheet, I or P, will be assigned to one of the two intervention or control groups, and the doctor will record that each patient belongs to intervention group or placebo group. It should be noted that the pulled out sheets will not be returned to the drawer until all four sheets have been pulled out. After accidentally pulling out all four sheets, all the sheets are returned to the drawer and the above procedure will be continued for the next four patients until the desired sample size is reached.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Hamedan University of Medical Sciences

Street address

Research Ethics Committees, Vice Chancellor for Research and Technology, Hamedan University of Medical Sciences

City

Hamedan

Province

Hamadan

Postal code

6517838678

Approval date

2020-11-07, 1399/08/17

Ethics committee reference number

IR.UMSHA.REC.1399.680

Health conditions studied

1

Description of health condition studied

Generalized Anxiety Disorder (GAD)

ICD-10 code

F41.1

ICD-10 code description

Generalized anxiety disorder

Primary outcomes

1

Description

Score of anxiety based on the Hamilton Anxiety Rating Scale

Timepoint

Measurement of severity and extent of improvement of anxiety at the beginning of the study (before the intervention) and 14, 28, 56 and 84 days after the start of use

Method of measurement

Hamilton Anxiety Rating Scale

Secondary outcomes

empty

Intervention groups

1

Description

Forty people in intervention group: Patients under treatment with SSRI at a specific dose (Sertraline oral tablets at the dose of 25 mg once daily and may be increased to 100 mg daily, or Citalopram 10 mg oral tablets once daily and may be increased to 40 mg daily) for 12 weeks + two 500 mg ginger capsules per day for 12 weeks Patients' visits may last from 20 minutes to an hour long of doctor's visit and questions and answers (filling out questionnaires) by the researcher. These visits will occur at the time of diagnosis, two weeks later, and also 4, 8, and 12 weeks after the first visit and diagnosis of GAD.

Category

Treatment - Drugs

2

Description

Control group: Patients under treatment with SSRI at a specific dose (Sertraline oral tablets at the dose of 25 mg once daily and may be increased to 100 mg daily, or Citalopram oral tablets 10 mg once daily and may be increased to 40 mg daily) for 12 weeks + two starch capsules per day (placebo) for 12 weeks Patients' visits may last from 20 minutes to an hour long of doctor's visit and questions and answers (filling out questionnaires) by the researcher. These visits will occur at the time of diagnosis, two weeks later, and also 4, 8, and 12 weeks after the first visit and diagnosis of GAD.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Farshchian (Sina) Hospital

Full name of responsible person

Lila Jahangard

Street address

Mirzadeh Eshqi St.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Shirin Sharifi

Street address

Vice Chancellor for Research and Technology, Hamadan University of Medical Sciences, in front of Mardom Park, Shahid Fahmideh St.

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Hamedan University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Sara Ataei

Position

Associate professor

Latest degree
Specialist
Other areas of specialty/work
Medical Pharmacy
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available